APPEAL BRIEF UNDER 37 C.F.R. § 41.37

TABLE OF CONTENTS

Page

1. REAL PARTY IN INTEREST 2
2. RELATED APPEALS AND INTERFERENCES 3
3. STATUS OF THE CLAIMS 4
4. STATUS OF AMENDMENTS 5
5. SUMMARY OF CLAIMED SUBJECT MATTER 6
6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL 7
7. ARGUMENT 8
8. SUMMARY 14
CLAIMS APPENDIX 15
EVIDENCE APPENDIX 17
RELATED PROCEEDINGS APPENDIX 18

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Aaron W. Janke et al.	Examiner: George R. Evanisko
Serial No.: 10/650,207	Group Art Unit: 3762
Filed: August 28, 2003	Docket: 279.093US3

For: HIGH IMPEDANCE ELECTRODE TIP

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on January 31, 2007, from the Final Rejection of claims 1-8 and 16-19 of the above-identified application, as set forth in the Final Office Action mailed on August 11, 2006.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC..

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on August 28, 2003 with claims 1-7. In an amendment and response filed September 24, 2004, claims 8-19 were added. In a Final Office Action mailed March 31, 2006, claims 9-15 were withdrawn. Accordingly claims 9-15 are presently withdrawn. Claims 1-8 and 16-19 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated August 4, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites: A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising: an electrode tip (20), a mesh screen (30) disposed at a distal end of the electrode tip, a surface at the distal end of the electrode tip, a helix (100) disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface. (Fig. 4A and page 16, lines 17-27). The helix includes non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient. (Page 20, line 14 - page 21, line 16; and page 25, lines 2-8). A guiding mechanism (70) for directing movement of the fixation device during travel, and a movement assembly (14, 50), said movement assembly for providing movement to said fixation device. (Fig 4A and page 17, lines 10-26).

Claim 16 recites: A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising: an electrode tip (800); a mesh screen (808) disposed at a distal end of the electrode tip; a surface at the distal end of the electrode tip; and a fixation helix (802) disposed within said electrode, said fixation helix adapted for travel along a radial axis of the electrode through said surface. (Fig. 6 and page 24, lines 2-5). The fixation helix includes a non-soluble insulating material (804) coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient. (Fig. 6 and page 20, line 14 - page 21, line 16; and page 24, lines 5-15; and page 25, lines 2-8).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-5, 7, and 8, were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074).

Whether claims 16-19 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074).

Whether claims 1, 2 , 3, 7, and 8 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Whether claims 16-19 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Whether claims 4 and 5 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Whether claim 6 was properly rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) or Bisping (US Pat. No. 4,886,074).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." Id. (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that:

> In order for the Examiner to establish a prima facie case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

B) Discussion of the rejection of claims 1-5, 7, and 8, under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074).

Appellant traverses the rejection of claim 1. Appellant believes claim 1 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Appellant cannot find in Bisping a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

The Office Action of 8/4/2006 cites a number of references on pages 5-7 that allegedly contain such subject matter and the Office Action states it would be obvious to combine the references with the Bisping reference. Appellant traverses. The references cited each have deficiencies and are not combinable with the Bisping reference as required under U.S.C. 103. Accordingly, the Office Action does not support a *prima facie* case of obvious for modifying the Bisping reference in view of these references.

The Office Action of 8/4/2006 asserts that "Dutcher shows in figures 5, 8, and 9, the use of a "plastic" drug plug covering part of the helix and therefore is one showing of many teachings the use of a "non soluble insulating material" coated on "at least a portion" of the helix "including an active ingredient"." (Page 5 of Office Action). This is a mischaracterization of the cited reference. The Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. (Fig. 5, col. 4, lines 46-65). The drug plug 138 is a plug of material filling the interior of wire 131. It cannot be properly construed as a coating of non-soluble insulating material. Accordingly, even if combined with Bisping, the combined structure does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

The Office Action of 8/4/2006 also asserts that "Altman describes in columns 14 and 15 the use of a polymer drug release device on a helix for therapeutic purposes." (Page 5 of Office Action). However, the polymer drug release device described in Fig. 16 of Altman is described as delivering drugs by "transporting particulate drugs through the polymer including but not limited to diffusion, osmotic swelling, and biodegradation of the polymer." (Col. 14, lines 12-15). Thus, it is not explicit in Altman that the polymer is non-soluble. Thus, Appellant cannot

find in Altman a non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

Moreover, Altman discusses different coatings for an implantable device which is for "effective elimination of an arrhythmogenic site." (Abstract). In contrast, Bisping relates to an implantable electrode type lead assembly. (Abstract). Thus, there appears to be no motivation to apply any of Altman's discussion to the lead of Bisping, since they are used for generally different purposes.

On page 6, the Office Action asserts that Hoffman et al '329 discusses a "drug non-soluble conforming insulative coating on a fixation device." Appellant cannot find in the Hoffman reference such subject matter. In contrast, Hoffman discusses a lead having a hydrogel coating. (Abstract). This is not a "non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient," as recited in claim 1.

Moreover, Appellant believes the Office Action has provided insufficient motivation to modify the Bisping reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01.

On page 6, in the response to Arguments section, the Examiner asserts that the motivation is to "provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc.) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to be still inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix." However, the Office Action does not establish that the Bisping reference needs such modifications or that one skilled in the art would be motivated to look for solutions to apparently non-existent problems. The Office Action merely applies hindsight analysis to find obviousness.

Claims 2-5, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

C) Discussion of the rejection of claims 16-19 under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074).

Appellant traverses the rejection of claim 16. Appellant believes claim 16 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Appellant cannot find in Bisping, a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

D) Discussion of the rejection of claims 1, 2 , 3, 7, and 8 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Appellant traverses the rejection of claim 1. Appellant believes claim 1 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Appellant cannot find in Grassi a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 1.

As noted above, the Office Action cites a number of references which allegedly contain such subject matter and the Office Action states it would be obvious to combine the references with the Grassi reference. Appellant traverses. The references cited each have deficiencies and are not inherently combinable with the Grassi reference. As discussed, the Dutcher reference discusses a sheath 133 on a wire 131 and a drug plug 138. However, even if combined, this does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, "the insulating material including an active ingredient." Altman discusses different coatings for an implantable device which is for "effective elimination of an arrhythmogenic site." (Abstract). However, Appellant cannot find in Altman a non-soluble coating, as claimed. Moreover, there appears to be no motivation to apply any of Altman's discussion to the lead of Grassi, since they are used for generally different purposes.

Also, Appellant believes the Office Action has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01.

Claims 2-3, 7, and 8 include each limitation of claim 1 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

E) Discussion of the rejection of claims 16-19 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Appellant believes claim 16 is not obvious over the cited reference since each limitation recited in the claim is not found in the cited reference. For instance, Appellant cannot find in Grassi, a fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient, as recited in claim 16. The discussion above for claim 1 is incorporated herein by reference.

Claims 17-19 include each limitation of claim 16 and are therefore also not obvious in view of the cited reference. Reconsideration and allowance is respectfully requested.

F) Discussion of the rejection of claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

Claims 4 and 5 depend from claim 1 is and are not obvious over the cited references for the reasons discussed about regarding claim 1. Also, Appellant believes the Office Action has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Reconsideration and allowance is respectfully requested.

G) Discussion of the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265) or Bisping (US Pat. No. 4,886,074).

Claim 6 depends from claim 1 is and is not obvious over the cited references for the reasons discussed about regarding claim 1. Also, Appellant believes the Office Action has provided insufficient motivation to modify the cited reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Reconsideration and allowance is respectfully requested.

8. SUMMARY

For the reasons argued above, claims 1-8 and 16-19 were not properly rejected under § 103. It is respectfully submitted that the art cited does not render the claims obvious and the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claims is respectfully requested.

Respectfully submitted,

AARON W. JANKE et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402

Date 4/30/07 By

Peter C. Maki
Reg. No. 42,832

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 30 day of April 2007.

Paula Sucha
Name

Signature

CLAIMS APPENDIX

1. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:

an electrode tip;

a mesh screen disposed at a distal end of the electrode tip;

a surface at the distal end of the electrode tip;

a helix disposed within said electrode, said helix adapted for travel along a radial axis of the electrode through said surface, the helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient;

a guiding mechanism for directing movement of the fixation device during travel; and

a movement assembly, said movement assembly for providing movement to said fixation device.

2. The distal tip electrode as recited in claim 1, wherein said helix comprises a fixation helix.

3. The distal tip electrode as recited in claim 1, wherein said movement assembly comprises a piston and a base.

4. The distal tip electrode as recited in claim 3, wherein the piston has a slot therein, and the base further comprises a knob, said slot for mating with said knob.

5. The distal tip electrode as recited in claim 4, wherein the slot is mated with said knob to form a stop mechanism for said fixation device.

6. The distal tip electrode as recited in claim 1, wherein the guiding mechanism includes a groove guide disposed within the mesh screen.

7. The distal tip electrode as recited in claim 1, wherein the active ingredient includes a medication.

8. The distal tip electrode of claim 1, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, or an analgesic.

16. A distal tip electrode adapted for implantation on or about the heart and for connection to a system for monitoring or stimulating cardiac activity, said electrode comprising:

an electrode tip;

a mesh screen disposed at a distal end of the electrode tip;

a surface at the distal end of the electrode tip; and

a fixation helix disposed within said electrode, said fixation helix adapted for travel along a radial axis of the electrode through said surface, the fixation helix including a non-soluble insulating material coated on at least a portion of its outer surface so as to conform to the outer surface of the helix, the insulating material including an active ingredient.

17. The distal tip electrode of claim 16, wherein the active ingredient includes a medication.

18. The distal tip electrode of claim 16, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, or an analgesic.

19. The distal tip electrode of claim 16, wherein the active ingredient includes an anti-inflammatant, an anti-biotic, an analgesic, a pain-reducing medication, a vitamin, or an anti-viral medication.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.